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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/917,710	08/26/1997	DANIEL P. BEDNARIK	1488.0450001	5107
22195	7590	01/05/2004	EXAMINER	
HUMAN GENOME SCIENCES INC			WEGERT, SANDRA L	
9410 KEY WEST AVENUE			ART UNIT	PAPER NUMBER
ROCKVILLE, MD 20850			1647	

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

## Office Action Summary

<p><b>Application No.</b> 08/917,710</p> <p><b>Examiner</b> Sandra Wegert</p>	<p><b>Applicant(s)</b> BEDNARIK ET AL.</p> <p><b>Art Unit</b> 1647</p>
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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 22 September 2003.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 20-29,38,39,49-58 and 60-73 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 20-29,38,39,49-58 and 60-73 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 26 August 1997 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.                            4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)
- 6) Other:

## **DETAILED ACTION**

### ***Status of Application, Amendments, and/or Claims***

The Request for a Continued Examination filed on 22 September 2003 under 37 CFR 1.53(d) is acceptable. An action on the RCE follows. Claims 1-19, 30-37, 40-48 and 59 have been cancelled. Claims 20-29, 38, 39, 49-58 and 60-73 are being examined in the instant Application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **Withdrawn Objections And/Or Rejections**

#### **Claim Rejections - 35 USC § 101 and 35 USC § 112, first paragraph-utility.**

The rejection of Claims 20-29, 38, 39, 49-58 and 60-73 under 35 U.S.C. 101 and 35 U.S.C. 112, 1st paragraph, as set forth at pages 4-9 of the Office Action of 17 October 2002, is withdrawn. Applicants submitted arguments and amended claims 20-29, 38, 39, 49-58 and 60-73 in the response of 22 September 2003.

**Claim Objections And/Or Rejections**

***35 USC § 112, first paragraph - scope of enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

Claims 20-29, 38, 39, 49-58 and 60-73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polynucleotide of SEQ ID NO: 1, encoding the polypeptide of SEQ ID NO: 2, does not reasonably provide enablement for all variants of SEQ ID NO: 1 or 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims are directed to the polynucleotides encoding the *IL-1R AcM* polypeptide of SEQ ID NO: 2, an accessory protein of the IL-1 receptor, as confirmed in the instant Specification (pages 19 and 20). The claims also embrace complementary nucleic acids, vectors comprising the polynucleotides, deposited host cells, and methods of recombinant expression of the peptide of SEQ ID NO: 2. The specification teaches recombinant expression of *IL-1R AcM* polypeptide, as well as evidence that the *IL-1R AcM* polypeptide of SEQ ID NO: 2 increases the binding affinity of IL-1 (see also: Smith, et al, 2003, Immunity, 18: 87-96). However, the scope of the patent protection sought by the Applicant as defined by the claims fails to correlate reasonably with the scope of enabling disclosure set forth in the specification for the following reasons:

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The specification discloses an enabled utility for the *IL-1R AcM* polypeptide of SEQ ID NO: 2. However, claims 20(f)- 20(n) and dependent claims encompass altering as much as 5% of the polypeptide encoded by SEQ ID NO: 1. However, as discussed in the previous Office Action (22 April 2003), the art shows that peptide families have members with high structural similarities but disparate functions. For example, Smith et al. (1997, Nature Biotechnology 15:1222-1223) demonstrate that there are numerous cases in which proteins having very different functions share structural similarity due to evolution from a common ancestral gene. Brenner (1999, Trends in Genetics 15:132-133) argues that accurate inference of function from homology must be a difficult problem since, assuming there are only about 1000 major gene superfamilies in nature, then most homologs must have different molecular and cellular functions.

Due to the large quantity of experimentation required to determine how to use all variants of SEQ ID NO: 1, the lack of direction or guidance in the specification regarding same - e.g., the lack of guidance regarding specific activity of SEQ ID NO: 2 with the modifications specified, the lack of working examples to all variants of SEQ ID NO: 1 and 2, the state of the art showing the unpredictability of function based on structural similarity of families of polypeptides, and the breadth of the claims which embrace innumerable variants of SEQ ID NO: 1 and 2, undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

Conclusion: Claims 20-29, 38, 39, 49-58 and 60-73 are rejected for the reasons listed above.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (703) 308-9346. The examiner can normally be reached Monday - Friday from 9:30 AM to 6:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Gary L. Kunz*  
**GARY KUNZ**  
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SLW  
12/21/03